

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of: ) Group Art Unit: 1623  
 )  
Chun-Ming Chen, Charles Carpenter, )  
Haoyi Gu, Au Naqui ) Examiner: M. Moran  
 )  
Serial No.: 08/942,369 ) Atty. Docket: 051091-1001  
 )  
Filed: October 2, 1997 )  
 )  
For: METHOD AND APPARATUS )  
FOR CONCURRENTLY DETECTING )  
PATHOGENIC ORGANISMS AND )  
ANTIMICROBIAL SUSCEPTIBILITY )

**REPLY BRIEF**  
**SUBMITTED PURSUANT TO 37 C.F.R. § 1.193**

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Sir:

Applicant (herein, "Appellant") submits this Reply Brief (in triplicate) in response to the Examiner's Answer mailed on February 11, 2004 ("Paper No. 69"). No fee is believed due with the Reply Brief. If this is incorrect, please charge or credit Deposit Account No. 50-0872 for the appropriate amount.

**REPLY TO EXAMINER'S ARGUMENT**

Several incorrect statements in the Examiner's Answer are apparent from a review of the papers. Some of these incorrect statements do not affect the outcome of this appeal. For example, the Examiner's assertion that Johnson discloses a medium is erroneous since Johnson discloses only devices. Johnson does make reference to the use of media in his devices, but discloses no particular media for use therein.

The Examiner statement at page 11, line 19 to page 12, line 4 of the Answer evinces a fundamental mis-reading of the claims. The Examiner states that the medium recited in the claims is a general medium because “[t]he claims specifically recite a medium ‘capable of sustaining growth of total microbial organisms,’ i.e., a nonselective medium.” In fact, the claims recite a method of detection that involves the use of a device with three distinct and different media that are used in at least three compartments of the device:

The first compartment (to which the Examiner refers) contains a medium capable of sustaining growth of total microbial organisms. It has never been asserted that this medium itself confers novelty to the invention. As has been explained throughout prosecution and in the Appeal Brief (p. 3, line 3), this compartment is one of at least three compartments in the device, and provides a “positive control.” A positive reading indicates microbial organisms are present in the sample but does not identify them to any particular class of bacteria.

The second compartment contains a uropathogenic specific medium, which was the subject of detailed discussion in prosecution. As recited in the claims, metabolism of a signal generating substrate and production of a detectable signal in this compartment indicates that a primary gram-negative uropathogen organism is present in the sample.

The third compartment contains an antimicrobial susceptibility interpretation medium, which is the same medium in the second compartment with the addition of one or more antimicrobial agents. Metabolism of a signal generating substrate and production of a detectable signal in this compartment indicates a lack of susceptibility of the organism to the antimicrobial agent contained therein.

Therefore, a proper reading of the claim must be directed to each limitation of the claims, including each of the three media recited in the claim, and not merely to the positive control for the device. The Examiner understands this legal concept (Examiner's Answer, p. 11, line 7 *et seq.*), but fails to apply it.

The claims were shown to be distinct from any combination of the cited art. During prosecution the Applicant presented laboratory data and evidence obtained using the Scientific Method illustrating that the media cited by the Examiner during prosecution did not meet the limitations recited in the claims. This evidence is also presented in the Appeal Brief at page 13. At page 12, line 10 *et seq.* of the Examiner's Answer the Examiner criticizes this data as not being directed towards the presently cited T-mod medium of Thaller. However, the data provided clearly distinguish MacConkey medium which is essentially identical to T-Mod in its relevant properties.

A brief review of the prosecution history illustrates the relevance and importance of these data, not only to the previously cited medium, but also to the medium of Thaller which the Examiner focuses on currently. At the outset of prosecution, the Examiner rejected the claims as obvious over Gibson in view of Sanders, and over Gibson in view of Sanders and Brocco (Office Action mailed 11/9/98). The Examiner later introduced the Johnson reference as a basis for an obviousness rejection (Office Action dated 4/28/99). The Applicants believed the Examiner was

incorrectly applying the law and brought those issues to appeal, submitting a Brief arguing the relevant issues. The Examiner responded by placing the case back into prosecution, adding a new rejection based on the Libman reference (Office Action mailed 7/05/2000). On Sept. 26, 2000, the Examiner mailed a supplementary Office Action, adding a new rejection based on the Manual of Clinical Microbiology (MCM) in combination with Johnson and Libman. The Examiner alleged that the person of ordinary skill would have a reasonable expectation of success in using the MacConkey agar disclosed by Libman and the MCM in the method of Johnson (Office Action mailed 9/26/00, p. 5, last line).

In order to demonstrate the falsity of this allegation, the Applicant devoted considerable expenses and resources to devising and carrying out a laboratory experiment demonstrating that the MacConkey agar fails to meet or render obvious the invention recited in the claims. These data were introduced in a Declaration of Dr. Chen, filed on November 15, 2001. The Declaration and accompanying data illustrate that, even making favorable assumptions for MacConkey agar, MacConkey agar could detect the primary gram-negative uropathogens in only about 60% of the samples compared to universally accepted methods that were used as standards. Its ability to detect resistance to antimicrobial agents was even worse. In the Office Action mailed 3/27/02, the Examiner then asserted that growth may have been occurring in the medium, but was merely undetectable (Office Action mailed 3/27/02, p. 2, line 20), despite the fact that the claims recited production of a detectable signal in said at least one compartment comprising a uropathogenic specific medium (As amended 3/26/01). Therefore the Examiner again failed to consider every limitation of the claim in applying rejections. The Examiner also introduced a new rejection based on the Thaller reference, which disclosed T-mod medium.

The Examiner now asserts that these data are irrelevant because the rejection is not directed to MacConkey agar (Examiner's Answer, p. 12, line 10 et seq.). But this ignores the disclosure of the Thaller reference, which states "Both the colony counts and sizes of the tested gram-negative strains showed no significant [sic] differences on T-mod and MacConkey media." (Thaller, p. 791, right column, ¶ 4). Since colony counts between gram-negative strains on the two media are not significantly different as Thaller reports, it is not reasonable to expect that T-mod medium will perform significantly different from MacConkey agar in the assay performed by Dr. Chen. It is rather reasonable to assume that indeed such a comparison is scientifically sound. Accordingly, the laboratory data provided by Dr. Chen demonstrate that T-mod medium also fails to meet the limitations recited in the claims. This finding is consistent with the description of Thaller of T-mod being a medium for **presumptive** identification and not for **near conclusive** identification. As explained in the Appeal Brief (page 8, ¶ B et seq.), prior art media such as MacConkey, T-mod, and others are isolation media for screening out some non-target organisms, but none have the selective power of the uropathogen specific medium of the invention. Thus, Thaller does not disclose a uropathogen specific medium as claimed and defined in the specification. The present invention provides **near conclusive** identification, because a "uropathogen specific medium" is defined as one "which allows only the growth of the primary urinary gram negative pathogens and allows substantially less growth of any other bacteria of a biological matrix" (specification, p. 12, line 11), and the "primary gram negative urinary pathogens" are defined as "the group of bacteria which cause at least 85-90% of the human and veterinary urinary tract infections" (specification, p. 10, line 19). The identification performed by Thaller is based not on ability to grow on a particular medium as claimed, but rather relies on a battery of biochemical tests performed on a previously purified colony, all of

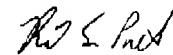
which must be performed by skilled laborers. It is precisely such colony purification and laborious expensive methods that the present invention can replace. (Appeal Brief, p. 17, line 5 et seq.). Thus, the present invention is a significant and patentable advance in the technology.

For all of the reasons explained above, in the Appeal Brief, and throughout the prosecution, it is respectfully requested that the rejections be withdrawn and the claims passed to allowance.

### CONCLUSION

In view of the above discussion, Applicant submits that claims 20-24, 26, and 31-43 are allowable. Applicant respectfully requests that they be allowed and passed to issue.

Respectfully submitted,



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